Western Research Company

Arizona Manufacturing Extension Partnership

Arizona MEP Assists Western Research Company in Development of Quality Standards

Client Profile:
Western Research Company, Inc has been developing high tech medical products since 1984 and specializes in the application of computer technology to the solution of clinically relevant problems. The company employs 15 people at its facility in Tucson, Arizona.

Situation:
Western Research Company, Inc. wanted to commercially develop a validated, manufacturable computer based imaging system for the quality control of blood samples obtained from newborns for genetic testing and monitoring. This system represents a new and innovative solution to the persistent problem of inadequate specimens arriving at the testing laboratories. The company's goal was to convert their Phase II prototype device, VeriSpot™, into a manufacturable system verifiable and validated by the U.S. Food and Drug Administration (FDA). The Arizona Manufacturing Extension Partnership (Arizona MEP), a NIST MEP network affiliate, in support of a federal grant initiative for technology companies, evaluated the awardee and the feasibility of their project and made recommendations to the National Science Foundation (NSF).

Solution:
Arizona MEP was instrumental in overseeing and closely monitoring this project and kept in constant contact with company representatives and with the subcontracted scientist, Dr. Donna Hartzfeld, to ensure the project was accurately documented and completed on schedule. To meet FDA device manufacturing requirements, the VeriSpot™ device required analysis from a regulatory perspective to determine the proper classification and product code to properly define the minimum manufacturing requirements of current Good Manufacturing Practices (cGMP) per FDA requirements. Western Research Company was given an overview as to the contents of all of the documents and was provided an on-site training as to the basic cGMP requirements for transferring from a research and development prototype into designing a prototype under the requirements of design controls and establishing the approach through a documented quality assurance plan. Additional tasks required a review of the prototype design, identification of potential GMP compliance, and the development of production cost control and quality assurance plans. The final task was to provide project updates and prepare and submit a final report. Specific outcomes generated by this effort included identification of manufacturing concepts, development of an initial manufacturing plan, testing of machines and tooling in a manufacturing environment, finalization of manufacturing processes and test criteria, and the beginning of full scale production meeting six sigma and other quality levels and initial production goals. As a result of Arizona MEP's assistance, all expectations were met, and Western Research Company was able to move forward to meet FDA manufacturing requirements for their medical device.

Results:
* Began full-scale production meeting six sigma, other quality levels and initial production goals.

Testimonial:
"Arizona MEP, and its affiliate, Dr. Donna Hartzfeld, were instrumental in preparing WRC for the application process to receive FDA approval of its newest medical device in final development. With the expertise of Dr. Hartzfeld and management skills of Arizona MEP, the project was a complete success and put WRC well on the road to manufacturing its newest device."

Eric R. Craine, PhD, President